EXPANDING CONTRACEPTIVE CHOICE:

Integrating Injectables into NGO Family Planning Services

A Guide for NGOs

Headquartered in Washington, DC, The Centre for Development and Population Activities (CEDPA) is an international nonprofit organization that seeks to empower women at all levels of society to be full partners in development. Founded in 1975, CEDPA supports programs and training in leadership, capacity building, advocacy, governance and civil society, youth participation and reproductive health.

The Enabling Change for Women's Reproductive Health (ENABLE) project works to strengthen women's capabilities for informed and autonomous reproductive health, Begun in 1998, ENABLE seeks to increase the capacity of NGO networks to expand reproductive health services and to promote a supportive environment for women's decision-making.

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THE enable PROJECT

ENABLING CHANGE FOR WOMEN'S REPRODUCTIVE HEALTH

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Photographs by, Rayne Loken, Tina Ravi and Mona Sharan

FOREWORD

The Government of India is committed to preventing unwanted pregnancies and meet unmet demand for contraceptive services and products, by ensuring the widest possible choice of and access to safe, effective and quality reproductive health care to every strata of the society, including the poorest of the poor. This was expressed in their signing of the International Conference on Population and Development, Cairo 1994, and in the National Population Policy, 2000.

Because, no currently existing contraceptive method is perfect for all women and couples, it is essential to provide as many alternatives of the safest and most effective methods known accompanied by counseling that provides complete and accurate information.

Since 1986 the injectable contraceptive DMPA has been legal in the country – it is approved by the Drug Controller of India and the Indian Council of Medical Research, and has been available commercially to women. The safety and effectiveness of DMPA use has been repeatedly documented over the past forty years in Western and developing countries.

India's closest neighboring countries, Bangladesh, Sri Lanka, Nepal and Pakistan, have successfully integrated injectables into family planning services thus giving all their citizens, including those who are poor and illiterate, access to an expanded choice of family planning methods. In India, several of the most prominent NGOs have successfully introduced injectable contraceptives into their family planning services providing clients with wider choices to met their reproductive health goals.

This booklet has been produced to enable NGOs to expand their basket of contraceptive methods and introduce injectables as an additional contraceptive option within their programs.

Appreciation goes to Dr. Bulbul Sood, MBBS, MNAMS, MPH, Program Management Specialist, CEDPA, who through her continued dedication to ensuring quality reproductive health services for the women of India has written this booklet. We would like to acknowledge Dr. Margaret Marshall, Senior Reproductive Health Advisor, CEDPA/Washington, for reviewing this booklet and Dr. Aparajita Gogoi, Advocacy and Communications Officer, CEDPA and Ms. Tina Ravi, Programme Associate, CEDPA for final editing and compilation of the booklet and putting it into a user-friendly format. This handbook deals with safety issues, misconceptions and programmatic issues for NGO Managers who are keen to introduce this method in their program.

We are also grateful to Ms Ashima Kumar for the design of this booklet and multicolourservices for printing this booklet.

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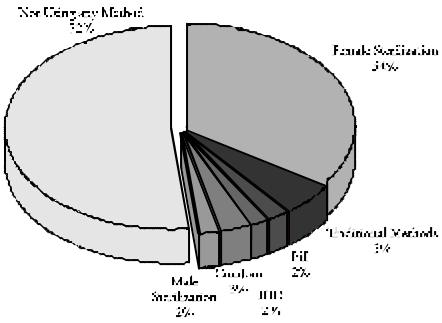
Expanding Contraceptive Choice

Women in India even today do not have many choices of contraceptives compared to women in the neighboring countries of Nepal, Sri Lanka and Bangladesh. The spacing methods available today through public health services are Oral Contraceptive Pills (OCPs), Condoms and IUCDs. Research suggests that a choice of several contraceptive methods, rather than a choice between one or two methods, is more likely to result in the use of a contraceptive method. As quality improves and more methods become available, more couples use contraception. For example, for each additional method that is widely available in a country, contraceptive prevalence, the percentage of married women using contraception, increases by an average 3.3 percentage points.

In India, use of spacing methods to increase birth intervals is very low. Yet we now know that a 3-5 year birth interval significantly reduces infant mortality.

Figure 1 : Family Planning methods used in India (NFHS-2)



An increase in the use of birth-spacing measures requires that women, men and couples are given comprehensive information about all contraceptive options and that there is support for personal decision making regarding family planning.

Wider contraceptive choices result in greater likelihood of programs meeting a couple's needs. Multiple methods make switching easier and may reduce method-specific discontinuation, improve user satisfaction and ensure the actual availability of a product in view of the erratic supply.

What is Expanded Informed Choice (EIC)

Expanded Informed Choice in context of family planning is specifically defined as follows:

- **Expanded:** an increase in the range and number of FP methods accessible to consumers
- **Informed:** clients have clear, accurate and specific information they need to make their own reproductive choices and they understand what their needs are

- **Choice:** clients have a range of family planning products to choose from; and clients make their own decisions

Why should my NGO expand the basket of contraceptives

Introduction of new technologies is an important way of expanding contraceptive utilization and addressing unmet need. The introduction of new technologies is also a means for improving quality of care by making available a wider choice of contraceptive options to potential users.

In order to expand informed choice, NGO programmes must add new technologies and provide quality services. With information and encouragement from NGOs and providers, women can make their own choices among family planning methods. They also learn what to expect and how to use their method. Some of the contraceptive choices available are emergency contraception, implants, natural family planning Methods like the 'Standard Days Method', spermicides, female condoms and injectables.

An NGO that is interested in considering expansion of the method mix is also signaling an awareness of the need for 'expanded informed choice' and service-related improvement.

Why consider Injectables as an additional choice in my program

About 14 million couples in over 100 countries throughout the world now use injectable contraceptives. Injectable contraceptives represent a safe and effective option for women seeking reversible contraceptive protection. Injectable contraceptives are popular with many women because they are highly effective and do not require daily effort or use at the time of sexual intercourse. Furthermore, some injectables can be used by women who cannot use methods that contain estrogen, including breast-feeding women. In some cultures, injectables are favored over other methods because they can be used without the knowledge of family and friends.

This booklet provides an overview of Injectable contraceptives and the major points we, as NGOs, need to know:

- what are injectable contraceptives and how they work
- how NGOs can add this method to the basket of contraceptive choices
- the effectiveness of injectable contraceptives and appropriate use of injectables
- client concerns about injectables
- basic elements of high - quality injectables contraceptive services

Injectable contraception is a safe, highly effective and legally approved method that is already being used by millions of women all over the world as well as in India (since 1994). Injectables are also a solution for those who do not wish to use other available spacing methods, do not want sterilization and do not have cooperative partners who will use condoms. Some of the non-health benefits of Injectables for a woman are: easy to use, does not interfere with sexual activity, does not require surgical procedure and insertion and is a private method.

Injectables are: easy to use, does not interfere with sexual activity, does not require surgical procedure or insertion and is a private method

Injectable contraceptives are the only progestin-only contraceptive available in India and therefore are also suitable for those women who are unable to use estrogen-containing contraceptives.

The two progestin-only injectables currently available in India are:

- Depot-medroxyprogesterone acetate (DMPA), which is administered once every three months.
- Norethisterone enanthate (NET-EN), which is administered once every two months.

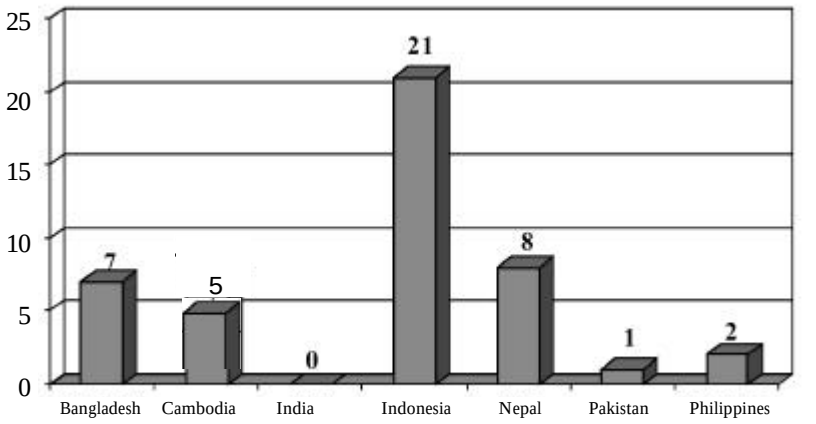
Table 1 : Progestin-only Injectables

Name	Active ingredients	Duration of effect	Commercial Brand	Manufacturer
DMPA	150 mg medroxy progesterone acetate	90 days	Depo-Povera	Pharmacia Upjohn
NET-EN	200mg norethisterone enanthate	60 days	Noristerat	German Remedies/ Schering

In India, DMPA is available through social marketing organizations like DKT, PSI and PSS and Pharmacia UpJohn, a Pharmaceutical company.

DMPA is a widely used injectable contraceptive because of its high contraceptive efficacy rate and safety. Since DMPA was introduced for contraception in the early 1960s, it has been approved in more than 90 countries where more than 30 million women have used it, including those with strict regulatory guidelines, including Sweden, France, Germany, New Zealand, the United kingdom and the United States.

Figure 2 : Percentage of Married Women of Reproductive Age using Injectable Contraceptives in Asia



Source: Measure DHS+ - http://www.measuredhs.com

DMPA became legal in India in 1994. Multi-centric trials of DMPA in India found it be very effective and safe.

Under the Drugs Act, DMPA can only be supplied to an MBBS/MD/MS physician. DMPA must be prescribed and administered under the direct supervision of a physician with full counseling of a client on all child spacing choices and the injectable contraceptive in particular to assess the most appropriate option.

Numerous NGOs in India are providing DMPA in their family planning services successfully, to mention a few - FPAI, PSS and CASP.

Facts about Injectables

What are injectable contraceptives

Injectable contraceptives contain female sex hormones that are injected into muscle and released into the blood gradually, thereby providing contraception over a period of time. Injectables are one of the most effective contraceptive methods.

Progestin-only injectables contain only progestin (which is a synthetic form of the female sex hormone progesterone). They are administered every two or three months, depending on the product.

DMPA is delivered as an aqueous suspension of microcrystals, which slowly dissolve and release the drug into the body. Contraceptive effects of progestogen persist for up to 14 weeks following injection.

Injectables are among the most effective reversible methods of contraception available

How do they work

Injectables stop the egg from leaving the ovary every month. They also make it difficult for sperm to enter the womb. They do this by thickening the mucus at the entrance to the womb. The woman must get an injection every two or three months.

Injectables do not provide protection against HIV infection and other sexually transmitted infections. Aside from abstinence, latex condoms offer the best protection against these infections.

How effective are injectable contraceptives

Injectables are among the most effective reversible methods of contraception available. In WHO studies, first-year failure rates have been approximately:

- 0.1 percent for DMPA
- 0.4 percent for NET-EN.

With injectables all a women needs to do is to receive her next injection on time. Because the effectiveness of injectables does not depend on daily user compliance, the pregnancy rates for injectables are very low even with typical use. As is evident from Table-2, use of injectables results in about the same pregnancy rates as sterilization, a non-reversible method. The only other reversible methods with similar effectiveness in typical use is the IUCD.

Table 2 : Effectiveness of family planning methods: Pregnancies per hundred woman years of use.

Family planning method	As commonly used	Used correctly and consistently
Vasectomy	0.2	0.1
DMPA and NET-En injectables	0.3	0.3
Female sterilization	0.5	0.5
Tcu -380 a IUD	0.8	0.6
Lactational Amnorrhoea method	2.0	0.5
Combined oral contraceptives	6-8	0.1
Male condoms	14	3
Coitus Interruptus	19	4
Diaphragm with Spermicide	20	6
Spermicides	26	6
No method	85	85

Source: Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use
(Second Edition): Reproductive Health and Research, WHO, Geneva

What are non-contraceptive health benefits of Injectable Contraceptives

Besides acting as a reliable contraception method, injectables offer several non-contraceptive health benefits in addition to preventing unwanted pregnancy and its associated health risks.

- Decrease risk of endometrial cancer. Studies conducted by WHO have shown that women who use DMPA are 60% less likely to develop endometrial cancer than women who have never used it. The protective effect lasts for at least 8 years after women stop using DMPA.
- Decrease menstrual blood loss, which may help to prevent anemia
- Decrease risk of ectopic pregnancy.
- Decreased risk of pelvic inflammatory disease (PID) [thickened cervical mucous prevents STD organisms from passing through the cervix.]
- Decreased frequency and severity of sickle cell disease [the progesterone in DMPA stabilizes the membrane of RBC's].
- Deceased frequency of epileptic seizures [it is found that progesterone in DMPA decreases the frequency of seizures]

- Reduced symptoms of endometriosis.
- Reduced risk of vaginal yeast infections.

The 40-year experience of using DMPA, sometimes in very high doses, gives great confidence in terms of the safety of the drug. There have been no disastrous problems when using 8-10 times or even a 100 times the contraceptive dose.

Both DMPA and NET-EN are available in India. Since clinical trials have already been done for DMPA in India, this information booklet will focus more on DMPA.

What are the constraints of injectable contraception

Like all other contraceptives, injectables too have some constraints, which are:

- Injectables do not protect against HIV infection and other sexually transmitted infections.
- Injectables cause changes in the menstrual cycle, such as spotting, irregular bleeding, or heavier bleeding. After two or three injections, many women stop having periods.
- Injectables cause some women to gain weight or have headaches.
- A woman using injectables may not be able to become pregnant for 6-12 months after she stops having the injections.

The 40-year experience using DMPA gives great confidence in terms of the safety of the drug

What are some misconceptions about injectables

Injectable contraceptives have great potential, but in India they also have been controversial. People need to know what is true or scientifically proven about injectables and what is incorrect or unproven. Also, they need to know the advantages and disadvantages of injectables and be able to compare them with those of other methods. By creating an accurate impression of injectables at the start, programs can avoid the more difficult task of correcting a wrong impression later.

Some of the Myths and Facts about injectables are given in Table 3.

Table 3 : Myths and Facts about Injectable contraceptives.

MYTH	FACT
Injectable contraceptives cause infertility.	DMPA does not permanently reduce fertility. However, it usually takes about four months longer for women to achieve pregnancy after discontinuing DMPA than after discontinuing other reversible contraceptive methods.
DMPA causes cancer.	WHO has declared DMPA safe. No effect on overall risk of breast cancer and invasive cervical cancer. DMPA protects against endometrial cancer & perhaps ovarian cancer. In fact, DMPA has been used for 40 years to treat endometrial cancer.
It is harmful if a woman stops menstruating (Amenorrheic) because then she will not be able to become pregnant again.	Amenorrhea is normal among DMPA users, just like women who do not have menstruation when they are pregnant. This does not mean that they cannot become pregnant again. When a woman stops DMPA she regains her ability to become pregnant.
If a woman does not menstruate, poisonous blood collects in her body.	Menstrual blood does not build-up or collect in her body instead the body does not produce menstrual blood when DMPA is used.
DMPA use leads to loss of bone density.	Findings to date suggest a relatively small and reversible effect, with no serious health risk for women of any age. Medical experts recommend no restriction for use by adolescents over 16; for adolescents under 16, the benefits of use exceed the possible risks.
Women who are breastfeeding should not use injectables.	Progestogen-Only injectables can be used by breastfeeding women at 6 weeks postpartum without any adverse effect to the nursing infant.
Injectable contraceptives transmit disease?	Injectable contraceptives are sterile preparations that are free from disease causing agents. Single-use needle and syringes are preferred. Where reusable needles and syringes are used, providers ensure that adequate sterilization procedures are used. They do not however protect against HIV/ AIDS or STIs.
In USA, FDA has not approved of DMPA	DMPA got FDA approval in USA in 1992 when WHO study produced reassuring findings about DMPA and Cancer.

What are some service delivery issues

To assess management capability, we need to find out:

- What are the intrinsic characteristics of injectable contraceptives as they relate to establishing service requirements (e.g., need for special facilities or equipment, record-keeping systems to remind users when duration of efficacy has passed, etc.).
- What systems must be in place to ensure that the NGO is at the appropriate level of preparedness for adequate service delivery?
- What is the NGO's ability to make the required adaptations to ensure quality of care in the introduction of this method (what is the burden on the system, and the non-monetary costs and capabilities of managing that burden? Does the programme offset the required monetary/non-monetary investment?)
- Will the sustainability of this method in the system depend on some form of cost recovery from the user or subsidization of the programme?
- What is the intensity of the user/provider interface required to mobilize demand (i.e., what efforts are required to disseminate information to make the method known?)

We should also consider: supervision, staffing, training, facilities, counseling/IEC needs, referral networks, record-keeping/follow-up systems, staff morale, outside resources required, and product and logistics management requirements (including registration, quality assurance and distribution).

Assess your organization's ability to integrate injectables into your family planning services using the checklist below.

My organization has:

- ☐ An MBBS, MD or MS **physician** employed or on contract.
- ☐ Continuous and reliable **service delivery systems** and sites.
- ☐ A **record-keeping** system to track clients.
- ☐ A means of **procuring, stocking and maintaining inventory**.
- ☐ A system for **social marketing**.
- ☐ A means of **safe disposal** for needles and syringes.
- ☐ **Sufficient funds** for initial stock procurement, training of staff and IEC.

If you have checked all the above, your organization is ready to initiate steps for introducing injectables

What are the program requirements

Given their established safety, ease of use, and options for delivery, injectable contraceptives can be offered by virtually any family planning service with a MBBS doctor. Introducing injectables as a new contraceptive method requires that providers be trained to screen and counsel clients and provide the method effectively. Also, effective supervision must be established, with supervisors overseeing both the technical and the counseling aspects of providing injectables.

The program must be able to reliably obtain adequate supplies of injectables, needles, and syringes, provide adequate storage facilities for the supplies, distribute them to providers, and ensure that products are not used after their expiration date.

The program should also consider offering only one type of injectable, rather than trying to maintain steady supplies of several products. It is not advisable to switch women from one injectable to another on a regular basis.

If a program decides to offer injectables or expand services, it needs to ensure that the choice of an injectable - and of every other program method - is continuously and widely available, provided safely, and offered without unnecessary restrictions on who can use it.

What should my organization do to introduce injectables in our FP program

Set up Injectable services: Introducing a new contraceptive and expanding services are formidable tasks. Your program will need to train providers, deliver supplies to clinics and other outlets, and start communication campaigns. Training, procurement and communication each can take 6 months or more to set up. Realistic estimates of the time required to prepare each component are essential for a well-coordinated introduction.

Set up a Clinic: Injectable contraceptives should be administered in clinics. However, with proper planning and monitoring, they can be provided at alternative locations, such as outreach service sites, such as mobile clinics or RCH Camps, provided the Physician is present. Injectables can be provided safely under the supervision of a physician - and require appropriate training on injectable technical guidelines, injection technique and counseling. The use of well trained providers can increase the acceptability and continued use of injectables.

Clinics will need to have the following for providing injectable services:

- Storage area that maintains a temperature of 15-30^0 C and protects from direct sunlight and humidity.
- Cotton wool and alcohol spirits to disinfect injection site
- Soap and water for provider to wash hands
- Puncture-proof container to dispose of needles and syringes, e.g. oil tin.

Ensure reliable supplies: Programs can ensure a reliable supply of injectables, needles, and syringes by:

- Consider offering only one type of progestin-only injectable. Offering more injectables increases choice but may strain logistics systems and confuse clients.
- Accurately projecting numbers of users - you may want to start with ordering 20-50 vials of injectables depending on the population you cover. Vials should be stored at temperature between 15-30^0 C but should not be frozen. All injectables should be stored at room temperature away from excessive heat and moisture. The shelf life of these vials are 5 years.
- Ordering well in advance. Keeping in view the distance to the nearest supply source, order should be placed a month in advance.
- Training providers in logistics (ordering and managing supplies),
- Logistics need to be taken into account in program planning and coordinated with events that can affect demand such as communication campaigns and provider training.

Counseling is the single most important aspect of injectable service delivery

In India, DMPA is available through social marketing agencies such as PSI, PSS and DKT and through the Pharmaceutical companies such as Pharmacia & Upjohn at varying prices. Your organization/program will need to decide on service fees for administering DMPA and charges for the product (e.g. wholesale versus retail prices, profit margins for the product to pay for community health workers' door-to-door services).

Establish appropriate eligibility criteria: Programs sometimes unnecessarily exclude women from using injectables. Programs may want to review clinical guidelines for injectables to allow the widest access consistent with good care. See Appendix 1 for women who can and cannot use DMPA.

Establish appropriate screening and counseling: Screening and counseling is important to ensure informed choice and use. With information and encouragement from providers, women make their own choices among family planning methods. They also learn what to expect and how to use their method. Having chosen injectables, women need to know when they can get injections and to expect menstrual changes. Counseling is the single most important aspect of injectable service delivery. Effective counseling reduces dropout rates significantly. See Appendix 3.

Prevent infection by properly handling used injection equipment: Increasing use of injectables challenges programs to prevent transmission of the AIDS-causing human immunodeficiency virus (HIV), hepatitis B, and other blood-borne infections to clients, clinic staff, and the public through contaminated needles and syringes. Injections for contraception are a small proportion of the total number of injections given, which include immunizations, vitamins, antibiotics, and others. However, since the injectable contraceptives come with disposable needle and syringe, they do not pose this problem. A safe method of disposal for the used needle and syringe should be available. The needle should be disposed of attached to the syringe and never re-capped, bent or broken.

Training providers, especially in counseling and safe injection technique: Training on injectables is an opportunity to improve the overall quality of family planning services. Training programs have covered basic information about injectables, counseling skills, and giving injections safely. The format and length of training depend on the background of providers. Experienced providers may need refresher training. They may not mention injectables when reviewing method choice with clients or they may not discuss side effects. Few clients starting or switching contraceptives receive information about injectables. Again, effective counseling that includes informing clients of the benefits and disadvantages, side-effects and correct usage of the method, is a must for quality injectable service delivery.

CASE STUDY

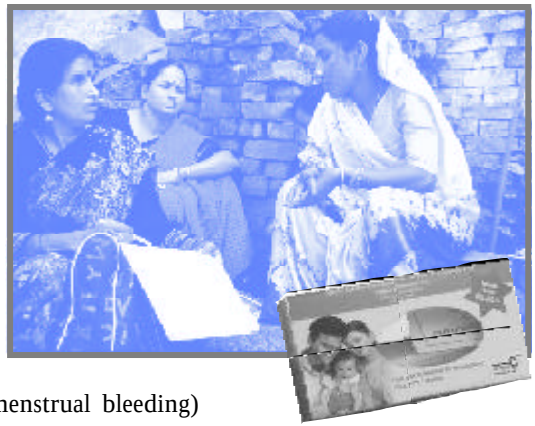
Noori, mother of five children, visited the family planning clinic run by CASP in Sangam Vihar, an urban slum in Delhi. Noori's youngest child was 45 days old. She did not want any more children but her husband and her family members would not agree to her using any kind of contraceptive including sterlization. They said it was against their religious beliefs. Noori was looking for a choice which would give her confidentiality.

At the clinic, after being counseled on all the contraceptive methods available, she chose Injectables because it was not only affordable and hassle-free, it gave her privacy and confidentiality. She is a satisfied client today who has just taken her 5^{th} dose.

The family planning clinic Noori visited is run by an NGO, CASP in Sangam Vihar, Delhi. They provide DMPA at their community clinic and community health guides provide door-to-door counseling and referral for DMPA as part of their comprehensive family planning services. DMPA service fees include administering of DMPA, counseling and cost for the product. In 18 months, CASP has reached a figure of over hundred satisfied clients from zero and the number is increasing every month. Some women have completed even 5 doses of injectables and are now involved in motivating other potential clients at the community level.

Addressing Client's Concerns

Providers should be aware of side effects that are associated with injectable contraceptives and how they can be effectively managed.



Disruption of Menstrual bleeding patterns

Women using Progestogen-only injectable contraceptives generally report experiencing one of the two side effects:

- Irregular menstrual bleeding patterns
- Amenorhea (the absence of menstrual bleeding)

Over 90% of women who use DMPA experience menstrual changes in their first year of use. Some have prolonged or heavier bleeding, others have irregular bleeding and spotting cycle and many eventually become amenorrhic.

After the first DMPA injection, over 40% of users experience prolonged or irregular bleeding. Following subsequent injections, these bleeding changes become less common, and after the first year of DMPA use, they are relatively uncommon. Infrequent bleeding and amenorrhea become more common as the duration of DMPA use increases. Nearly 60% of women are amenorrheic after one year of DMPA use, and about 80% are amenorrheic after two years of use. However after women stop using DMPA, normal menses return. NET-EN disrupts bleeding patterns somewhat less than DMPA.

Women's concerns over prolonged or heavy bleeding should never be disregarded or considered unimportant

Management of Bleeding through Counseling

Counseling is the most important tool for the management of prolonged, irregular, or heavy bleeding resulting from DMPA use. Women who are considering using DMPA and NET-EN should be counseled that such changes in bleeding are normal and expected, and that they are not signs of disease or health problems.

Also, women's concerns over prolonged or heavy bleeding should never be disregarded or considered unimportant. Counseling often may be the only intervention necessary. However, if the user continues to be concerned, or of the bleeding is severe, medical treatment or discontinuation of DMPA may be

necessary. At this stage health workers should help the client choose another suitable contraceptive.

Management of Bleeding through Treatment

Several medical options are currently available to manage prolonged or heavy bleeding with continued DMPA use :

- If a woman experiences very heavy bleeding, it is important for the provider to rule out pregnancy, miscarriage, or gynecological problems (such as fibroids). Providers must recognize that they may need to refer such women to higher levels of health care. One treatment option is to administer a low-dose combined oral contraceptive for seven to 21 days, if estrogen is not contraindicated. The recommended dose is one pill a day or, in more severe cases, one pill every 12 hours. If prolonged (more than 8 days) or heavy bleeding persists, this regimen may be tried two or three times before the next injection.
- Providers should be aware that uterine evacuation, such as dilatation and curettage (D&C) is not indicated or necessary for DMPA related bleeding.
- Another approach is to administer a non-steroidal anti-inflammatory drug, such as Ibuprofen, to decrease uterine bleeding. The most commonly recommended dose is 200 milligrams three or four times a day until bleeding diminishes.
- One more approach is to administer the next DMPA injection sooner than it would normally be scheduled. This may reduce bleeding and accelerate the onset of amenorrhea. The early injection should be given no sooner than four weeks after the previous injection.
- Women experiencing prolonged or heavy bleeding may be given iron supplements to prevent anaemia and should be encouraged to take foods rich in iron.
- Aspirin should not be used, because its anticoagulant effect can promote bleeding

Amenorrhea associated with DMPA use does not present a health risk or require medical treatment

Management of Amenorrhea

Some women consider amenorrhea to be an advantage of using DMPA, but others may be concerned about this side effect. Amenorrhea associated with DMPA use does not present a health risk or require medical treatment.

If the provider has no reason to suspect pregnancy, counseling and reassurance are the only tools needed for management of amenorrhea. Women need to be reassured that amenorrhea is normal for DMPA users and does not indicate pregnancy. Women also may need to be reassured that the absence of menses

does not mean that toxic blood is building up inside their bodies, that they have become infertile, or that they have reached premature menopause.

Other reported side effects

In addition to menstrual disruption, other side effects have been reported. Most injectable users report weight gain. The WHO clinical trial found an average weight gain of 1.5 to 2 kilograms in the first year of use. Only 2% of women stop using DMPA because of weight gain.

A small number of women have reported additional side effects, including headaches, dizziness, breast tenderness, body aches, nervousness, fatigue, and acne. Although these side effects may be troublesome and are possibly unacceptable, there is no evidence that they are dangerous to health, and not all can be directly attributed to use of injectables.

Good Counseling is Key

The counseling a woman receives from her provider can have an important effect on the willingness to tolerate side effects. Health workers should not dismiss complaints about side effects, however, when a woman decides to discontinue injectables because of side effects, her health care provider should help her find a suitable alternative contraceptive.

Studies carried out in many countries over the last thirty years have shown no long term health risks for users of progestogen only injectables

What are the possible health risks of injectable contraceptives

Large studies carried out in many countries over the last forty years have shown no long term health risks for users of progestogen only injectables.

DMPA, the most widely used injectable- has been the most extensively studied, particularly the possibility of relationships to risk of cancer, loss of foetal exposure and effect on bone density.

Cancer and DMPA

Clinical studies have found no association between DMPA use and cervical, ovarian, or liver cancers and have confirmed a substantial protective effect against endometrial cancer.

No Overall Increased Risk of Breast Cancer with DMPA

Studies conducted by WHO and a study in New Zealand examined breast cancer risk in women using DMPA. These studies both concluded that use of DMPA does not affect the overall risk of breast cancer.

These studies also showed that DMPA users had a somewhat increased risk of breast cancer during their first five years of DMPA use. Women who had used DMPA for longer than five years had no increased risk of cancer. One possible explanation for the increased risk during the first five years of DMPA use is detection bias, meaning that since these women see their doctors more frequently than non-users, it is likely that their cancer would be identified earlier. Another possible explanation is that DMPA may accelerate the growth of pre-existing tumours, again resulting in an earlier diagnosis.

A woman who is breastfeeding should wait until her child is six weeks old before using DMPA

Women in their first five years of DMPA use, tend to be younger women, whose risk of breast cancer without DMPA use is very low. So even with the increased risk associated with DMPA, their risk of breast cancer is still quite low.

No Increased Risk of Invasive Cervical Cancer with DMPA

The large WHO multinational study and several smaller studies have found no increased risk of invasive cervical cancer in women who have used DMPA. This is true regardless of how long or how recently a woman has used DMPA.

The WHO study also showed that DMPA users have a slightly increased risk of developing cervical carcinoma *in situ*, which is a non-invasive cancer limited to the epithelium of the cervix. The risk seems to increase with duration of DMPA use, but declines after 10 years. It also may be attributable to detection bias.

Effect on foetal exposure

There have been no adverse effects of fetal exposure to injectables. Studies of teenage children who were exposed to DMPA *in-utero* show no significant differences in health, growth, or sexual development compared to other children.

Effect on breastfeeding

DMPA has been used extensively by women who were breastfeeding. Studies have shown that DMPA has no adverse effects on:

- The onset or duration of lactation.
- The quantity or quality of breast milk.
- The health and development of nursing infants.

DMPA is excreted through breast milk. A breastfeeding infant swallows a small amount of DMPA, which enters the child's circulatory system. In newborn infants, the liver may not yet be mature enough to metabolise the DMPA received through breast milk. Therefore, as a precaution, it is recommended that a woman who is breastfeeding wait until her child is six weeks old before using DMPA.

Effect of DMPA on Bone Density

Researchers have questioned whether long term DMPA use could reduce bone density, particularly in young adolescents. Findings to date suggest a relatively small and reversible effect, with no serious health risk for women of any age. At present, medical experts recommend no restriction on use of injectables by adolescents over age 16; for adolescent under age 16 the benefits of injectables are believed to generally outweigh the possible risks associated with their use.

Providers should refer to Appendix 2 for answers to frequently asked questions by the clients.

Conclusion

Success of family planning programs depends on maximizing access and quality of the services. Providing a wide range of contraceptive choices improves acceptance rates.

- Over 14 million women use injectable contraceptive in 100 countries and DMPA is the most widely used injectable contraceptive in the world.
- DMPA is backed by 40 years of experience, as treatment and contraceptive.
- Studies show DMPA is safe, effective and easy to use. It has no deleterious effects on the fetus or lactation.
- There are no reports of infertility following DMPA use.
- Counseling is the most effective tool for managing the bleeding side effects of DMPA.
- DMPA may be initiated when it is reasonably sure that the woman is not pregnant.
- DMPA may be given up to 4 weeks early or up to 4 weeks late without affecting its efficacy.
- In many countries DMPA injection is given by nurses and para-medical workers.

Your organization can improve its family planning services by expanding choice and increasing access to additional safe and effective methods.

References

- DMPA: Myths and Realities: Federation of Obstetric and Gynaecological Societies of India (FOGSI)
- Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use (Second Edition): Reproductive Health and Research, WHO, Geneva
- EngenderHealth - www.engenderhealth.org
- JHU/CCP - www. jhuccp.org
- WHO - http://www.who.int/reproductive-health/publications
- Injectable Contraceptives: Contraceptive Technology Update Series: Family Health International
- Measure DHS+ - http://www.measuredhs.com

Appendix 1

Appropriate use of Injectables

Which women can use injectables safely

Most women can use injectables safely and effectively even if they:

- are breastfeeding (starting as soon as 6 weeks after childbirth)
- smoke cigarettes
- have no children
- are of any age including adolescents and over 40 years
- are fat or thin
- have just had abortion or miscarriage

Women with following conditions also generally can use DMPA

- Benign breast disease
- Mild headaches
- Mild or moderately high blood pressure
- Iron deficiency anemia
- Blood clotting problems
- Varicose veins
- Valvular heart disease
- Irregular menstrual periods
- Malaria
- Schistosomiasis
- Sickle cell anemia
- Thyroid disease
- Uterine fibroids
- Epilepsy
- Tuberculosis

Are there women who should not use injectable

From practical perspective, injectable contaceptives are not appropriate for women who cannot see health worker for regular injections (every 2- 3 months, depending upon the formulation) or cannot accept changes in menstrual bleeding patterns.

The following are considered reasons to avoid giving DMPA

- Undiagnosed vaginal bleeding.
- Known/suspected pregnancy.
- Known/suspected breast cancer.

- ActiveThrombophelibitis
- History of embolism or cerebrovascular disease.
- Active liver disease/dysfunction.
- Known hypersensitivity to Depo Provera.
- Women who want to become pregnant in the next 6 months.

Guidelines for starting the use of injectables

Specific Situation	Common Current Guidelines
For women having menstrual cycle	Anytime after making sure that she is not pregnant. Note: If she starts during the first 7 days of her menstrual period, and if she is still bleeding, no back-up method is needed for extra protection. If she is not bleeding or she starts on or after day 8 of her menstrual period, she should use condoms or spermicide or avoid sex for the next 48 hours.
Breastfeeding	As early as 6 weeks after childbirth. If she is only partially breastfeeding and the newborn receives other food or drink, 6 weeks after childbirth is the best time to start. If she waits longer, fertility may return.
After childbirth if not breastfeeding	Immediately or anytime in the first 6 weeks after childbirth. She does not have to wait for her menstrual period to return. If she has taken DMPA shots within 6 weeks of childbirth, she should ascertain that she is not pregnant. If she is not certain, she should avoid sex or use condoms or spermicide until her first period returns.
After miscarriage or abortion	Immediately or in the first 7 days after either first or second trimester miscarriage or abortion. Later, anytime when she is sure that she is not pregnant.
After stopping another method	Immediately

Source: DMPA: Myths and Realities: Federation of Obstetric and Gynaecological Societies of India (FOGSI)

If the provider cannot be reasonably sure the woman is not pregnant, she should be given a backup contraceptive method such as condoms and asked to return for her first injection when she starts her next menses.

Appendix 2

Frequently Asked Questions

Does injectables protect against getting or passing on STD/ HIV

No. Injectable contraceptives do not protect women from sexually transmitted diseases (STDs), including HIV, the virus that causes AIDS. All women and men who are at risk of STDs and HIV should receive information about STDs/ HIV and counseling about strategies to lower their STD/HIV risk, including the use of latex condoms, even if they rely on injectables as their primary contraceptive method.

When does fertility return in injectable contraceptive users

Once injectable contraceptives are metabolized by the body, over a period of 1-3 months, depending on the type of injectable used. Because of this, injectables generally involve a delay in return to fertility upon discontinuation. Although some women conceive immediately after a missed DMPA injection, on average, fertility returns about 9 months after last injection.In NET-EN users, fertility returns on average about 8 months after last injection.

Health workers should counsel users to expect a eight month delay in return to fertility after the last injection

Health workers should counsel users not to expect an immediate return to fertility after stopping the injections.

Do injectable contraceptives affect future fertility

No. Injectable contraceptives are fully reversible. They do not build up inside the body or cause women to become to become infertile Although, injectable contraceptives generally involve a delay in return to fertility, conception rates among former injectable users after one year are comparable to sers of other reversible methods.

There is no difference in the time it takes to return to fertility between women who have used injectable contraceptives for many years and women whose duration of use has been shorter.

Are there women who should not use injectable

From practical perspective, injectable contaceptives are not appropriate for women who cannot return to her service provider for regular injections (every

2- 3 months, depending upon the formulation) or cannot accept changes in menstrual bleeding patterns.

The following are considered reasons to avoid giving DMPA

- Undiagnosed vaginal bleeding.
- Known/suspected pregnancy.
- Known/suspected breast cancer.
- ActiveThrombophelibitis
- History of embolism or cerebrovascular disease.
- Active liver disease/dysfunction.
- Known hypersensitivity to Depo Provera.
- Women who want to become pregnant in the next 6 months.

When can a woman begin to take DMPA and NET-EN

Before initiating DMPA, the provider should be reasonably sure the woman is not pregnant. One can be reasonably sure a woman is not pregnant if she has no signs and symptoms of pregnancy and if one of these criteria is met:

- She is within first seven days after onset of menses.
- She has not had intercourse since the last menses.
- She is using contraception correctly and consistently.
- She is within seven days postpartum.
- She is within four weeks postpartum, if she is not breastfeeding.
- She is within six months postpartum, if she is fully breast feeding and is amenorrheic.

How frequently do women need to have injections

Studies of injectables are going on to determine the degree of flexibility that can be allowed while maintaining maximum contraceptive effectiveness. Currently the recommended injection schedules are as follows:

- DMPA is given every 90 days, the injection can be given 4 weeks early or 4 weeks late.
- NET-EN is given every 60 days, the injection can be given 2 weeks early or 2 week late.

If a woman is late for an injection, the health worker must be reasonably sure she is not pregnant before giving the next injection.

Appendix 3

Screening Flowchart for Injectable Contraceptives

Please ask the client all of these questions and check the correct box.

1. **Is your menstrual period late and do you think you could be pregnant now?** No ☐ Yes ☐
2. **Have you ever had a stroke, blood clot in your legs or lungs, or heart attack?** No ☐ Yes ☐
3. **Do you have diabetes (sugar in your blood)?** No ☐ Yes ☐
4. **Do you have or have you had breast cancer?** No ☐ Yes ☐
5. **Do you have a serious liver disease or jaundice (yellow skin or eyes)?** No ☐ Yes ☐

↓ If the client answers NO to all the above questions, continue with question 6.

↓ If the client answers YES to any of the above questions, refer her to a clinic/ physician and give her condoms to use in the meantime.

6. **Do you have bleeding between menstrual periods, which is unusual for you, or bleeding after intercourse (sex)?**

↓ If the client answers NO to all the questions, she can use DMPA, but to find out when she can start, continue with question 7.

↓ If the client answers YES, she can be given DMPA now, but refer her to clinic/ physician for further evaluation of the bleeding. Continue with question 7.

7. **Are you currently breastfeeding?**

↓ If client answers NO, go to question 9.

↓ If the client answers YES, go to question 8.

8. **Is your baby less than 6 weeks old?**

↓ NO. If client is breastfeeding a baby 6 weeks old or older and her menstrual periods have not returned, she can be given DMPA now. If her menstrual periods have returned, go to question 9.

↓ YES. If client is breastfeeding a baby less than 6 weeks old, instruct her to return for DMPA as soon as possible after the baby is 6 weeks old.

9. Has it been more than 7 days since the beginning of your last menstrual period?

NO. If the client began her last menstrual period within the past 7 days, she can be given DMPA now.

YES. If the client started her last menstrual period more than 7 days ago, and if:

- She has been using an effective method of contraception (including abstinence), she can be given DMPA now, but instruct her that she must use condoms or abstain from sex for the next 7 days. Give her condoms.

OR

- She has not been using an effective method of contraception (including abstinence), she must wait until her next period to be given DMPA. Give her condoms to use in the meantime.

Source: Stang A, Schwingl P, Rivera R. New contraceptive eligibility checklists for provision of combined oral contraceptives and depot-medroxyprogesterone acetate in community-based programmes. 2000;78(8):1015-23 from Family Health International.

EXPLANATION OF DMPA CHECKLIST QUESTIONS

Is your menstrual period late and do you think you could be pregnant now

This question has two parts - both of which should be asked together, and the answer "yes" must apply to both parts of the question. One or more missed periods in combination with the woman's own report that she is or might be pregnant is required before a woman should be referred to a higher-level health care provider.

Have you ever had a stroke, blood clot in your legs or lungs, or heart attack

This question is intended to identify women with already known serious vascular disease, not to determine whether women might have an undiagnosed condition. Women who have had any of these conditions will commonly have been told that they have had this condition and will answer "yes," if appropriate.

Do you have diabetes (sugar in your blood)

The intention of this question is to identify women who know that they have diabetes, not to assess whether they may have an undiagnosed condition.

Do you have or have you had breast cancer

The intention of this question is to identify women who know they have had or currently have breast cancer.

Do you have a serious liver disease or jaundice (yellow skin or eyes)

The intention of this question is to identify women who know that they currently have a serious liver disease and to distinguish between current severe liver disease (such as severe cirrhosis or liver tumors) and past liver problems (such as treated hepatitis).

Do you have bleeding between menstrual periods, which is unusual for you, or bleeding after intercourse (sex)

The intention of this question is to distinguish between normal bleeding changes (such as those associated with the use of another contraceptive method), and those that are different or unusual for the client, and to identify postcoital bleeding (since bleeding after intercourse may indicate an abnormality). The use of DMPA does not make these conditions worse but may change the bleeding pattern. Unusual bleeding changes can underlie a serious condition that should be evaluated by a higher-level health care provider, but DMPA use need not be delayed.

Are you currently breastfeeding

Is your baby less than 6 weeks old

These questions are intended to identify women who are breastfeeding babies under 6 weeks of age. A breastfeeding woman can initiate DMPA 6 weeks after her baby is born.

Has it been more than 7 days since the beginning of your last menstrual period

The intention of this question is to determine when the client should start DMPA. If she has just started her menstrual cycle and is within days 1 to 7 of the first day of bleeding, she can start the method immediately. If it is more than 7 days since her first day of bleeding, she will need to wait until her next menstrual period begins before she can be given DMPA. Give her condoms to use in the meantime.

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